

Notice of Allowability

Application No.

09/830,837

Examiner

William W. Moore

Applicant(s)

SEIDAH ET AL.

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1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 11 August 2006 and the interview conducted 21 September 2006.
2. ☒ The allowed claim(s) is/are 30, 31, 35, 36, 41-49, 53, 56, 65, 67, 72, 73, 81-83, 95-97, 101-103, 107-109, and 117-119.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Cancel claims 40 and 80.

Amend claims 36, 37, 41, 44-49, 53, 101-103 and 117-119 thus:

36. (Amended) An isolated nucleic acid consisting of a nucleic acid sequence encoding the polypeptide as defined in claim 30.
37. (Amended) An isolated nucleic acid consisting of a nucleic acid sequence encoding the polypeptide as defined in claim 31.
41. (Amended) ~~A~~ The recombinant expression vector comprising the isolated nucleic acid of claim 36 ~~40, wherein which is an expression vector~~ a soluble subtilisin-kexin SKI-1 enzyme consisting of the amino acids from position 187 to 996 of SEQ ID NO:6 is produced upon expression of said vector in a host cell.
44. (Amended) An isolated ~~A~~ recombinant host cell comprising the recombinant vector as defined in claim ~~41~~ 40.
45. (Amended) A method of producing a soluble subtilisin-kexin SKI-1 enzyme ~~the polypeptide of claim 30~~, which comprises the steps of:
culturing a recombinant host cell expressing a recombinant vector ~~a nucleic acid~~ as defined in claim ~~41~~ 36 in an expression-supportive culture medium; and
recovering the soluble subtilisin-kexin SKI-1 enzyme ~~from polypeptide of claim 30 in the culture medium.~~
46. (Amended) A method for cleaving a substrate for a subtilisin-kexin SKI-1 enzyme, which comprises ~~the step of:~~ contacting said substrate with a polypeptide consisting

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of amino acids 187-996 of SEQ ID NO:6 for a time sufficient and in conditions adequate for such cleavage to occur,

whereby cleavage of the substrate occurs;

~~with the proviso that said substrate is not a sterol regulatory element binding protein (SREBP).~~

47. (Amended) A method for producing a protein or a peptide from a precursor which is an enzymatic substrate for a subtilisin-kexin SK1-1 enzyme, which comprises ~~the steps of:~~

a) contacting said precursor with a polypeptide consisting of amino acids 187-996 of SEQ ID NO:6 for a time sufficient and in conditions adequate for such cleavage to occur; and

b) recovering said protein or peptide;

~~with the proviso that said substrate is not a sterol regulatory element binding protein (SREBP).~~

48. (Amended) The method of claim 47, which takes place in a host cell and wherein step a) further comprises the step of transfecting an isolated host ~~a~~ cell with a nucleic acid expressing said SKI -1 enzyme.

49. (Amended) The method of claim 48, wherein said host cell expresses said precursor or is transfected with a nucleic acid expressing said precursor.

53. (Amended) A purified peptide which comprises the sequence as set forth in SEQ ID NO:13.

101. (Amended) An isolated nucleic acid consisting of a nucleotide sequence encoding the polypeptide of claim 95.

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102. (Amended) An isolated nucleic acid consisting of a nucleotide sequence encoding the polypeptide of claim 96.
103. (Amended) An isolated nucleic acid consisting of a nucleotide sequence encoding the polypeptide of claim 97.
117. (Amended) A recombinant vector comprising the isolated nucleic acid defined in claim 101, wherein a polypeptide that consists of the amino acids from position 18 to 188 of SEQ ID NO:6 is produced upon expression of the vector in a host cell.
118. (Amended) A recombinant vector comprising the isolated nucleic acid defined in claim 102, wherein a polypeptide that consists of the amino acids from position 18 to 196 of SEQ ID NO:6 is produced upon expression of the vector in a host cell.
119. (Amended) A recombinant vector comprising the isolated nucleic acid defined in claim 103, wherein a polypeptide that consists of the amino acids from position 18 to 169 of SEQ ID NO:6 is produced upon expression of the vector in a host cell.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Ann E. Rabe on 21 September 2006.

The following is an examiner's statement of reasons for allowance:

The examiner's amendment above clarifies the descriptions of certain elements of claims 36, 37, 41, 45-49, 53, 101-103 and 117-119, retaining the term "subtilisin-kexin SKI-1 enzyme" in every claim that refers to an SKI-1 protease following claims 30 and 31, and removing the "proviso" clauses in claims 46 and 47 because both methods require the use of a product that is free of the prior art of record herein – the soluble SKI-1 protease that consists of amino acids 187-996 of SEQ ID NO:6 – making the "proviso" clause superfluous. Claims 48, 49 and 53 are amended to ensure that the subject matter described conforms to the requirements for statutory subject matter stated in 35 U.S.C. § 101, and claims 101-103 and 117-119 are amended to ensure that

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isolated nucleic acids of claims 101-103 encode no more than the peptides of claims 95-97, thus cannot reach the prior art, integral, subtilisin-kexin_SKI-1 enzyme of Brown et al., of record, and that vectors of claims 101-103 expressing such nucleic acids result in the production of the polypeptides of claims 95-97.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
21 September 2006


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER